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FTC Focus: How Scrutiny Of PBMs And Insulin May Play Out

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This article is part of a monthly column that considers the significance of recent Federal Trade Commission announcements about antitrust issues. In this installment, we discuss the FTC's complaint on PBMs' conduct around insulin.

No stranger to controversy about their role in pharmaceutical pricing, pharmacy benefit managers are headed for more.

On Sept. 20, the Federal Trade Commission filed an administrative complaint against the three largest PBMs — Caremark, Express Scripts Holding Co. and Optum Inc. — and their affiliates, alleging anticompetitive conduct in violation of the FTC Act with respect to insulin products.

The complaint follows the agency's interim staff report issued earlier this summer, which highlighted the trend of horizontal consolidation among PBMs as well as vertical integration with other key players at other levels of the industry, like pharmacies — and insurers. These concerns continue in the FTC's new complaint.

But PBMs will not go gently into the night.

On Sept. 17, Express Scripts, one of the six largest PBMs featured in the July report, sued the FTC in the U.S. District Court for the Eastern District of Missouri, denouncing the report as unsupported innuendo "under a false and defamatory headline and accompanied by a false and defamatory press release."

The issue between the FTC and PBMs is certainly joined and now playing out across multiple jurisdictions and the press. We review this latest bout of antitrust scrutiny over PBMs and the potential implications for PBMs and others in the industry.

A Quick Introduction to Pharmaceutical Markets

PBMs are not new, though their purposes, practices and market power have changed over time. Dating back to the 1960s, PBMs were originally tasked with administering insurance claims from plan beneficiaries.

Since then — they have expanded to play a key role in reimbursing pharmacies for costs associated with acquiring drugs, creating formulary lists and negotiating rebates with drug manufacturers in connection with formulary lists. Through these distinct but related roles, PBMs are able to affect the prices of prescription drugs.

PBMs and Manufacturers

PBMs are a primary interface with manufacturers — that is, the companies that develop and produce drugs — and two activities sit at the core of the contractual relationship between

PBMs and manufacturers: negotiating drug prices and establishing formulary lists.

PBMs negotiate drug prices, including rebates, with manufacturers in part through healthcare plan formulary placements — i.e., whether a drug is "preferred" under a particular insurance plan.

Placement of a drug on a formulary list can affect which pharmacies have access to the drug, and whether insurance networks will cover the cost of a particular manufacturer's drug and to what degree.

PBMs and Pharmacies

Pharmacies, of course, are where patients fill their prescriptions. Pharmacies receive formulary lists from PBMs and sometimes a portion of what PBMs receive from either manufacturers, rebates or healthcare plans — payments for drugs. In this way, PBMs stand between manufacturers and pharmacies, negotiating with both.

PBMs and Healthcare Plans

Healthcare plans contract with PBMs to assist with the administration and reconciliation of prescription drug claims. They also contract with PBMs regarding formulary lists and receive a portion of the rebates in some instances.

The FTC's Prior Scrutiny of PBMs

PBMs have long attracted the attention, and ire, of the FTC. In March 1999, the FTC issued a report that noted the horizontal and vertical consolidation trends of the pharmaceutical industry, with a focus on PBMs.[1] The 1999 report also highlighted PBMs' rebate practice and noted the potential that the size of a manufacturer's rebate could override patient demand for which drugs a particular pharmacy decides to carry.

A subsequent 2005 report was more favorable to PBMs,[2] however, examining trends in mail-order pharmacies and determining that the presence of PBMs did not result in higher costs for consumers. Then, a May 2021 report on so-called rebate walls called attention to the industry's use of rebates conditioned on a drug's continued placement as "preferred" on a formulary list.[3]

In June 2022, the FTC issued a policy statement regarding the impact of exclusionary rebates on insulin products.[4] In that statement, the FTC took the position that these practices could be actionable under the Sherman Act, the FTC, the Robinson-Patman Act and the Clayton Act's ban on exclusive dealing.

The FTC then issued orders under Section 6 of the FTC Act, which empowers it to require a business to file "reports or answers in writing to specific questions" to clarify the "organization, business, conduct, practices, management and relation to other corporations, partnerships and individuals."[5]

The FTC issued 6(b) orders to the top six PBMs. In May 2023, the FTC issued additional 6(b) orders to three group purchasing organizations, which are organizations that negotiate rebates on behalf of groups of PBMs.[6] Then came the 2024 report.

The 2024 Report

The report emphasized the expanding role that PBMs play in the market, including their role in setting drug prices, negotiating rebates from manufacturers and influencing which drugs are covered by certain insurance plans.

The report highlighted that the top six PBMs make up more than 90% of the market, while the top three process more than 80% of prescriptions. A few days after the report was issued, the press reported that the FTC planned to file a lawsuit against the three largest PBMs.

The report previewed the FTC's lawsuit, identifying a number of concerns.

Vertical Integration

The FTC continued its focus on vertical consolidation issues, noting integration of PBMs with other market participants — namely pharmacies — raises concerns about the potential for unfair pricing practices. Specifically, because PBMs negotiate the price and presence of prescription drugs at certain pharmacies, the report suggested that PBMs could be offering favorable pricing terms for its affiliated pharmacies as opposed to independent, unaffiliated pharmacies.

The report examined this practice through case studies involving pricing practices for two drugs used to treat prostate cancer and leukemia, noting that pharmacies affiliated with PBMs can be paid 20 to 40 times more for these drugs than independent pharmacies.

Steering Concerns

The report also highlighted how PBMs can steer patients toward affiliated pharmacies by restricting access to certain drugs. This can be accomplished by the labeling of certain drugs as "specialty," which carries with it the opportunity to restrict availability to certain "specialty" pharmacies.

However, evidence provided in support of this conclusion in the report is limited. In the report's view, the use of a "specialty" label for a given drug restricts where it can be purchased, in effect steering patients toward certain providers.

Increased Barriers to Entry

Though not explicitly mentioned in the report, its findings can be read to suggest that the horizontal consolidation and vertical integration of PBMs pose barriers to entry for smaller, less-resourced PBMs.

PBMs Strike Back: The Express Scripts Suit

The Sept. 17 complaint filed by PBM Express Scripts in the Eastern District of Missouri against the FTC challenges the report. The complaint repeated accusations that others have levied against the FTC during Chair Lina Khan's tenure as commissioner: namely, that it has become a politicized, partisan institution.

A key allegation is that the FTC has changed course, contradicting its own 2005 report, in which the FTC concluded that PBMs did not have a negative impact on prices for consumers. The FTC has already previewed its response: The 2005 report may not be reflective of current market conditions and therefore no longer represents the agency's position.

Specifically, the Express Scripts complaint asserts: (1) Fifth Amendment due process violations based on an allegedly biased approach to the report; (2) violation of the Administrative Procedures Act on the grounds that the report is arbitrary and capricious and not "in the public interest"; and (3) defamation claims under state law.

The complaint also alleges that the structure of the FTC violates Article II of the U.S. Constitution, because its commissioners are not freely removable by the president.

The FTC Returns With a Complaint of Its Own

Shortly after the Express Scripts complaint, the FTC filed its own, on Sept. 20. It alleges that the largest PBMs engage in anticompetitive conduct through unfair rebating practices, thereby raising the price of insulin drugs.

According to the FTC, this is the result of a feedback loop flowing from PBMs' use of formulary placements to pursue higher rebates from manufacturers, excluding new entrants who cannot get on the formularies and driving prices up. These higher prices, the FTC argues, increase certain out-of-pocket costs to some patients. On the FTC's account, this "chase-the-rebate strategy" purposefully drives prices up for the benefit of PBMs.

It is no accident that the FTC chose insulin as its poster child to challenge PBMs' rebating practices. Insulin prices grabbed headlines, spurred long-running antitrust litigations, and were the subject of a 2021 Senate inquiry, the FTC's June 2022 policy statement and, of course, President Joe Biden's recent executive order capping the Medicare prices for insulin.

If the FTC can make its case with insulin, however, the result has potential implications for the broader pharmaceutical industry.

Reflections on the Future

Given the pace of litigation, the battle between the FTC and PBMs will undoubtedly rage for years to come. The Express Scripts complaint may be the first ever judicial challenge to an FTC interim report.

If it has any modicum of success, others who find themselves targeted in a report may add potential litigation to their playbook, which flips the playbook against the FTC by giving the target its choice of forum and, if the FTC files its own suit, forcing it to litigate in parallel venues.

There are also takeaways for recipients of 6(b) orders. If Express Scripts is correct in its allegations, the resulting report was not an objective set of findings, but rather preordained.

If 6(b) recipients are concerned about similar treatment, they could consider ways to be more aggressive in their responses to the FTC and lay the groundwork for objections and arguments that could be used to challenge any resulting report.

The confluence of the report, Express Scripts' complaint and the FTC's lawsuit also raises questions about the purpose and practices of the Interim 6(b) reports, which the FTC does not often release. Can they be subject to legal challenge, and if so, can they undermine the efficacy of any follow-on FTC complaint on the subject?

PBMs are certainly taking a shot at establishing such precedent, which will undoubtedly set a precedent for others who find themselves adverse to the FTC.

On the other hand, the FTC's case, though targeted on a single drug, attacks the core of PBMs' business models and a central aspect of drug pricing. Follow-on litigation can be expected. It will be watched closely, as potential plaintiffs look at whether rulings on rebating practices for insulin may be repeated and expended to other drugs.

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[1] https://ftc.gov/system/files/documents/reports/pharmaceutical-industry-discussion-competitive-antitrust-issues-environment-change/the_pharmaceutical_industry_-_march_1999.pdf.

[2] https://ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf.

[3] https://ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf.

[4] https://ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

[5] 15 S.C. § 46(b).

[6] https://ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen.

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